

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/820,099</p>	<p>Applicant(s) MCEWEN, SIMON</p>	
	<p>Examiner SUSAN HANLEY</p>	<p>Art Unit 1651</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 29.
Claim(s) objected to: 1, 4-16 and 18-24.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: 30 and 31.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 8/12/08
13. ☒ Other: see continuation.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651

Continuation of 13.
Election/Restrictions

Newly submitted claim 31 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The product claims (Group I) and the method of use claim (claim 30; Group II) were restricted in the requirement mailed 10/5/06. The restriction was based on the showing that the product of Group I can have different unrelated medical uses that are distinct from the claimed treatment of arthritis. New claim 31 is also directed to the treatment of arthritis. Hence, claim 31 is related to claim 30.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 31 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 30 remains withdrawn because it will only be rejoined when claim 1 or claim 11 are found to be allowable.

Continuation of 3. Note: The addition of new limitations for a method of treating arthritis (claims 30 and 31) with the composition of claims (1, 11 and 29, respectively) raises new considerations for search and examination. For example, if the amendment had been entered, the newly added limitations for the method would have to be searched against the prior art. Furthermore, the use of mouse models as reliable indicators for human arthritis treatment, effective amounts of glucuronidase and collagen as well as efficacy would have to be evaluated against the currently cited references. Hence, the non-entered amendment raises new issues for consideration of enablement for a therapeutic method, a search of new prior art as well as consideration regarding the currently cited prior art.

Continuation of 11, does NOT place the application in condition for allowance because: Applicant's arguments are non-persuasive. Applicant argues that the restriction requirement is improper and that claim 30 should be rejoined with the product which was found to be allowable (in Applicant's view) and all claims to the non-elected process must depend from or otherwise require all of the limitation of an allowable claim to be eligible for rejoinder. Applicant submits that claims 30 and 31 depend from claims 1 and 29, respectively. Applicant declares that claim 29 is allowable and expects that claim 1 is allowable. Applicant concludes that claims 30 and 31 should be rejoined with the invention of Group I.

Responding to Applicant's argument that claim 1 must be allowable since claim 29 was indicated as allowable, the scope of these claims differ considerably and the amendments to claim 1 must also be considered. Responding to Applicant's assertion that claims 1 and 29 should be rejoined with claims 30 and 31, respectively, only claim 29 has been found to be allowable. Claim 31 did not exist in the originally filed claims. Hence, it could not be considered for rejoinder in the last Office action. Claim 31 is a new claim that raises new grounds of consideration *supra*. Regarding the rejoinder of claims 1 and 30, claim 1 has not been found to be allowable, hence there is no rejoinder at this time.

Claim Rejections -35 USC 112

Claims 1, 4-16 and 18-24 stand rejected under 35 USC 112, first paragraph.

Applicant argues that the cancellation of claims 2 and 3 and the amendments to claims 1 and 11 obviate the rejection. Applicant alleges that the Examiner has acknowledged that the claimed treatment as a whole is enabled due to the citation of page 10 in the first Office action.

Applicant's argument has been considered but is unpersuasive of error. Applicant's allegation that the incorporation of claims 2 and 3 into claims 1 and 11 renders claims 1 and 11 allowable fails to address the factual basis of the rejection. Claims 2 and 3 represent the elected species which were previously examined. Applicant has failed to address the merits of the rejection which included the rejection of claims 2 and 3, now incorporated into claim 1. The acknowledgment by the Examiner that the data on page 10 of the specification supports the allowability of claim 29 was made to indicate that the exact composition of claim 29 appears to unexpectedly overcome the lack of enablement supported by the prior art. However, the allowability of a composition supported by surprisingly results is limited specifically to what is supported by the specification. In the instant case, the disclosure supports the limited scope of claim 29 but is not extended to the broadly claimed compositions of claims 1 and 11. Applicant has failed to rebut the enablement rejection for the broadly claimed inventions of claims 1 and 11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651